Food and Drug Administration
Center for Drug Evaluation and Research
Summary Minutes of the Advisory Committee for Pharmaceutical Science

July 20, 2001
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, Maryland

PARTICIPANTS

Members Present
Stephen R. Byrn, Ph.D., Chair
Judy Boehlert, Ph.D.
Joseph Bloom, Ph.D.
John Doull, M.D., Ph.D.
Nair Rodriquez-Hornedo, Ph.D.
William J. Jusko, Ph.D.
Vincent H. L. Lee, Ph.D.
Jürgen Venitz, M.D., Ph.D.

Consumer Representative
Gloria L. Anderson, Ph.D.

Invited SGE Consultant
William H. Barr, Pharm.D., Ph.D.

Invited Academic Guests
Patrick J. McNamara, Ph.D.
Shinya Ito, M.D.
M. Peggy Neville, M.D
Marvin C. Meyer, Ph.D.

Invited Industry Guests
Francis J. Martin, Ph.D.
Leon Shargel, Ph.D., R.Ph.

Executive Secretary
Nancy Chamberlin, Pharm.D.

FDA
Mei-Ling Chen, Ph.D.
Yuan-yuan Chiu, Ph.D.
Kofi A. Kuml, Ph.D.
Lawrence J. Lesko, Ph.D.
Arzu Selen, Ph.D.
Arthur B. Shaw, Ph.D.

NIH Participants
Klaus Gawrisch, Ph.D.
Burton J. Litman., Ph.D.

These summary minutes for the July 20, 2001 meeting of the Advisory Committee for Pharmaceutical Sciences were approved on Oct 2, 2001.

I certify that I attended the July 20, 2001 of the Advisory Committee for Pharmaceutical Sciences and that these minutes accurately reflect what transpired.

Nancy Chamberlin, Pharm.D.
Executive Secretary

Stephen R. Byrn, Ph.D.
Chair

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Invited Guests Participants
(Robert) Gary Hollenbeck, Ph.D.
Williams Kerns, D.V.M., M.S.,D.A.C.V.P.
Leon Lachman, Ph.D.
Marvin C. Meyer, Ph.D.
Jeanne Moldenhauer, Ph.D.
Kenneth H. Muhvich, M.S., Ph.D.
G.K. Raju, Ph.D.

Executive Secretary
Nancy Chamberlin, Pharm.D.

FDA
Wallace P. Adams, Ph.D.
Yuan-yuan Chiu, Ph.D.
Badrul Chowdhury, M.D.,Ph.D.
Eric P. Duffy, Ph.D.
Ajaz S. Hussain, Ph.D.
Capt. David Hussong, Ph.D.
Robert J. Meyer, M.D.
Bryan S. Riley, Ph.D.
Vilayat A. Sayeed, Ph.D.
Helen N. Winkle

Invited Industry Guests
Leon Shargel, Ph.D., R.Ph.
Gordon Holt, Ph.D.

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Nancy Chamberlin, Pharm.D.
Executive Secretary

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Stephen R. Byrn, Ph.D.
Chair

On July 19, 2001, the Advisory Committee for Pharmaceutical Science met in an open public session at the CDER Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, Maryland. Prior to the meeting, the members, consultants and invited guests had reviewed background material from the FDA. There were approximately 110 people in attendance.

At 8: 34 a.m., the meeting was called to order by, Stephen R. Byrn,Ph.D., Chair. This was followed by the conflict of interest statement, read by Nancy Chamberlin, Pharm. D., Executive Secretary, and the introduction of meeting participants.

Helen Winkle introduced the topics and presented FDA's objectives for the meeting.

Subcommittee Reports:

Orally Inhaled Nasal Drug Products (OINDP)
Vincent H. L. Lee, Ph.D., provided an overview of *The June 1999 BA/BE Guidance for Nasal Aerosols and Nasal Sprays.* This was followed by Badrul Chowdhury, M.D., Ph.D.'s presentation of *Difficulties in Showing a Dose-Response with Locally-Acting Nasal Sprays and Aerosols for Allergic Rhinitis.* Robert J. Meyer, M.D., presented *Clinical Study Options for Locally Acting Nasal Suspension Products.* Then Wallace P. Adams, Ph.D., reported on the conclusions from the July 17, 2001 OINDP Subcommittee Advisory Committee Meeting during his presentation of *The June 1999 BA/BE Guidance for Nasal Aerosols and Nasal Sprays: Recommendations of the OINDP Subcommittee.* Following the presentations was the committee discussion regarding clinical BE studies for comparison of local delivery of suspension nasal products for allergic rhinitis.

Nonclinical Studies (NCSS)
John Doull, M.D., Ph.D. updated the committee on the NCSS subcommittee and introduced the speakers for the two Expert Working Groups (EWGs). Gordon Holt, Ph.D. reported on the NCSS Fact Finding Cardiotoxicity Expert Working Group. While Williams Kerns, D.V.M., M.S.,D.A.C.V.P., reported on the NCSS Vascular Injury Expert Working Group. Then Helen Winkle, presented the *Nonclinical Studies Subcommittee Next Steps.*

Chemistry, Manufacturing and Controls
Yuan-yuan Chiu, Ph.D., presented *An Introduction and Overview of Risk-Based CMC Review.* Eric P. Duffy, Ph.D., reported on *the Risk-Based CMC Review AAPS Workshop Report: Drug Substance Issues.* Vilayat A. Sayeed, Ph.D., provided an *Update on Risk-Based CMC Review.* While David Hussong, Ph.D., provided the *Risk-Based CMC Microbiology Review and the Risk-Based CMC Review, GMP Breakout Sessions Summary.* Then Yuan-yuan Chiu, Ph.D., concluding with her presentation of the *Next Steps: Risk-Based CMC Reviews.* The presentations were followed by committee discussion of the questions for Risk-Based CMC Reviews.

Optimal Applications of At-line Process Controls on Pharmaceutical Production
Ajaz S. Hussain, Ph.D., presented on *Optimal Applications of "In-Line" or "At-Line" Manufacturing Controls in Pharmaceutical Production.* Then G. K. Raju,. Ph.D., reported on

Continuous Quality Verification (CQV). After discussion by the committee, there was a proposal to create an in-line and at-line control production subcommittee under the Pharmaceutical Science Advisory Committee.

Microbiology
David Hussong, Ph.D., presented on *New Microbiological Technologies.* Then Bryan S. Riley, Ph.D., gave the *Microbial Limit Testing Technology Overview. Followed by* Kenneth H. Muhvich, Ph.D., describing *Validation Issues of Rapid Methods.* While Jean Moldenhauer, Ph.D., provided a presentation on *Rapid Microbiology Methods: Industry Concerns.* After discussion by the committee, there was a proposal for a creating a microbiology subcommittee under the Pharmaceutical Science Advisory Committee to look at new technology and validation issues.

Open Public Hearing Session:
The AAPS Inhalation Technology Focus Group (ITFG)/ International Pharmaceutical Aerosol Consortium (IPAC) Collaboration Technical Teams representatives presented information on *Bioequivalence Studies and Other Recommendations for Orally Inhaled and Nasal Drug Products.* David Radspinner, Ph.D., Aventis Pharma, presented an *Update of ITFG/IPAC-RS Dose Content Uniformity (DCU) Working Group Progress.* Carole Evans, Ph.D., Magellan Laboratories, presented *an Update on Progress of Particle Size Distribution (PSD) Working Group and Tests and Methods Team.* James D. Blanchard, Ph.D., Aradigm Corporation, presented an *Update on Progress of Leachables and Extractables Team.* Then Joel Sequeira, Ph.D., Schering Plough Research Institute, presented the concluding presentation on *Bioequivalence Studies for Locally Acting Nasal Drug Products* which contained comments from the BA/BE Team on the Issue of Dose Response.

The meeting adjourned on July 19, 2001 at 5:02 p.m.

For more detailed information see the verbatim transcript of this meeting on the FDA's Docket Management Branch Website address:
HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm

Prepared by:
Nancy Chamberlin, PharmD., Executive Secretary
The Advisory Committee for Pharmaceutical Science